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PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|---|------------------------|---------------------------|
| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/759,695 |
| | Filing Date | January 16, 2004 |
| | First Named Inventor | Gerianne Tringali DiPiano |
| | Art Unit | 3763 |
| | Examiner Name | |
| Total Number of Pages in This Submission | Attorney Docket Number | FEM 105 |

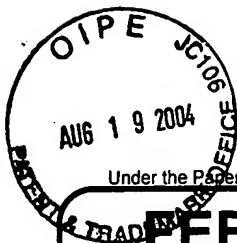
| ENCLOSURES (Check all that apply) | | |
|---|--|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Search report from PCT/US2004/001131; 1 Page of Form PTO-1449 and 6 references |
| Remarks _____ | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | |
|--|---|
| Firm or Individual name | Patrea L. Pabst, Esq., Reg. No. 31,284 Pabst Patent Group LLP 400 Colony Square, Suite 1200, Atlanta, GA 30361 |
| Signature | |
| Date | August 17, 2004 |

| CERTIFICATE OF TRANSMISSION/MAILING | |
|---|-----------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. | |
| Typed or printed name | Ronna Berman |
| Signature | |
| Date | August 16, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 0

Complete if Known

| | |
|----------------------|---------------------------|
| Application Number | 10/759,695 |
| Filing Date | January 16, 2004 |
| First Named Inventor | Gerianne Tringali DiPiano |
| Examiner Name | |
| Art Unit | 3763 |
| Attorney Docket No. | FEM 105 |

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit
Account
Number
Deposit
Account
Name

50-3129

Pabst Patent Group LLP

The Director is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity | | Small Entity | | Fee Description | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | | |
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | |

SUBTOTAL (1) (\$) 0

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims | | Extra Claims | | Fee from below | Fee Paid |
|--------------------|--------------------|--------------|---|----------------|----------|
| Independent Claims | Multiple Dependent | | | | |
| 9 | 2 | -20* = 0 | X | | |
| | | -3** = 0 | X | | |

| Large Entity | | Small Entity | | Fee Description |
|--------------|----------|--------------|----------|--|
| Fee Code | Fee (\$) | Fee Code | Fee (\$) | |
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$) 0

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

| Fee Code | Fee (\$) | Fee Code | Fee (\$) | Fee Description | Fee Paid |
|----------|----------|----------|----------|--|----------|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for ex parte reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 0

SUBMITTED BY

| | | | | | |
|-------------------|-----------------|-----------------------------------|-----------------|-----------|----------------|
| Name (Print/Type) | Patrea L. Pabst | Registration No. (Attorney/Agent) | 31,284 | Telephone | (404) 879-2151 |
| Signature | | Date | August 13, 2004 | | |

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gerianne Tringali DiPiano, John Andrew Ziemniak, and Joel Martin
Bartholomew

Serial No.: 10/759,695

Art Unit: 3763

Filed: January 16, 2004

Examiner:

For: *VAGINAL OR RECTAL APPLICATOR*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit a Supplemental Information Disclosure Statement, including 1 page of Form PTO-1449, copies of the 6 documents cited therein, and a copy of the International Search Report, mailed December 7, 2004, in the corresponding PCT application PCT/US2004/001131.

It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 50-3129.

U.S.S.N.: 10/759/695
Filed: January 16, 2004
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Certification Under 37 C.F.R. §1.97 (e)(1)

Each item of information contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Supplemental Information Disclosure Statement.

U.S. Patents

| <u>Number</u> | <u>Issue Date</u> | <u>Patentee</u> | <u>Class/Subclass</u> |
|---------------|-------------------|-----------------|-----------------------|
| 5,462,740 | 10-31-1995 | Evenstad et al. | 424/436 |
| 5,531,703 | 07-02-1996 | Skwarek et al. | 604/187 |
| 6,224,573 | 05-01-2001 | Yeager et al. | 604/181 |

Foreign Documents


| <u>Number</u> | <u>Publication Date</u> | <u>Patentee</u> | <u>Country</u> |
|---------------|-------------------------|-----------------------------------|----------------|
| 1 248 636 | 10-06-1971 | Ortho Pharmaceutical Corporation | GB |
| 0 263 976 | 04-20-1988 | Fujisawa Pharmaceutical Co., Ltd. | EP |
| 0 633 033 | 01-11-1995 | Survival Technology, Inc. | EP |

U.S.S.N.: 10/759/695
Filed: January 16, 2004
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Patrea L. Pabst', is written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: August 17, 2004

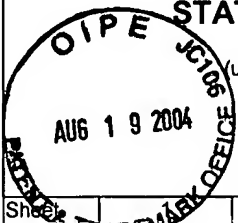
PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
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Atlanta, Georgia 30361
(404) 879-2151 (Telephone)
(404) 879-2160 (Fax)

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Complete if Known | |
|  | | Application Number | 10/759,695 |
| | | Filing Date | January 16, 2004 |
| | | First Named Inventor | Gerianna DiPiano |
| | | Group Art Unit | 3763 |
| | | Examiner Name | |
| Sheet 1 of 1 | Attorney Docket Number | FEM 105 | |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|--------------------|--------------------------------------|---|--------------------------------------|---|
| Examiner Initials* | Cite No. ¹ | US Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| | | 5,462,740 | | Evenstad et al. | 10-31-1995 | |
| | | 5,531,703 | | Skwarek et al. | 07-02-1996 | |
| | | 6,224,573 | | Yeager et al. | 05-01-2001 | |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|--------------------------------------|---|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office. ³ | Number ² | Kind Code ⁵ (if known) | | | | |
| | | GB | 1 248 636 | | Ortho Pharmaceutical Corporation | 10-06-1971 | | |
| | | EP | 0 263 976 | | Fujisawa Pharmaceutical Co., Ltd. | 04-20-1988 | | |
| | | EP | 0 633 033 | | Survival Technology, Inc. | 01-11-1995 | | |
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| Examiner's Signature | | | | | Date Considered | | | |

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| Examiner's Signature | Date Considered |
|----------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

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